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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,633	04/09/2004	Zia Yassinzadeh	021872-001900US	9024

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
ANDERSEN, MICHAEL T	
ART UNIT	PAPER NUMBER
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,633	YASSINZADEH, ZIA	
	Examiner	Art Unit	
	M. Thomas Andersen	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *22-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction Requirement

Applicant's election without traverse of Group I (Claims 1-21) drawn to a method for hemostasis in the reply filed on 1/11/2007 is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) received on 8/26/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Specification

The disclosure is objected to because of the following minor informalities: page 13, line 1, "the" should be inserted between "when balloon".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-13, 15-17, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers, U.S. 5,486,195.

Myers discloses a method for hemostasis of a puncture site in a blood vessel, comprising providing a compression member having an expansible element disposed at its distal end, inserting the compression member through an opening in a skin surface,

positioning a distal end of the expansible element at a predetermined distance away from a wall of the blood vessel, and expanding the expansible element within the tissue tract and against subcutaneous tissue.

The expansible element is only engageable against subcutaneous tissue surrounding the blood vessel wall. See Figure 8.

The predetermined distance is in a range from about 0.05 inch to about 0.5 inch. See col. 4, line 54 – col. 5, line 6.

The expansible element comprises a balloon.

Expanding the balloon comprises at least one of axial or radial dilation of the balloon so as to cause compression of the subcutaneous tissue surrounding the blood vessel wall.

Expanding also comprises inflating a superior aspect of the balloon greater than an inferior aspect of the balloon. See figure 8.

Expanding also comprises inflating a distal face of the balloon at an angle to the compression member similar to an angle formed between the compression member and the blood vessel. See figure 8.

The balloon can be said to comprise a conical shape in its deployed configuration. See figure 8.

The distal end of the balloon is concave. See figure 8.

The method further comprises providing a locating member having a proximal member having an expansible member disposed on the distal end thereof. See figure 8.

The locating member is inserted through the opening in the skin in the puncture site prior to or simultaneously with compression member insertion.

The method provides temporary hemostasis of the puncture site with a plug 38 that is capable of being coupled to the distal end of the locating member. See figure 5D.

The locating member is then contracted and withdrawn. See figure 5D.

Meyers further discloses delivering ultrasound energy to the puncture site. See col. 4, lines 65-67.

Myers also discloses delivering a clot promoting agent to the puncture site. See col. 2, lines 53-55.

Claims 1-2, 5-6, 8, 10, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker, U.S. 2003/0055454.

Zucker discloses a method for hemostasis of a puncture site in a blood vessel, comprising providing a compression member having an expansible element disposed at its distal end, inserting the compression member through an opening in a skin surface, positioning a distal end of the expansible element at a predetermined distance away from a wall of the blood vessel, and expanding the expansible element within the tissue tract and against subcutaneous tissue. See figures 1, 3G

The expansible element is only engageable against subcutaneous tissue surrounding the blood vessel wall. See Figure 3G.

The expansible element comprises a balloon.

Expanding the balloon comprises at least one of axial or radial dilation of the balloon so as to cause compression of the subcutaneous tissue surrounding the blood vessel wall.

Expanding also comprises inflating a distal face of the balloon at an angle to the compression member similar to an angle formed between the compression member and the blood vessel. See figure 3G.

Expanding comprises unfolding concentric folds of the balloon. See figure 3C.

The method further comprises providing a locating member having a proximal member having an expansible member disposed on the distal end thereof. See figure 3G.

The locating member is inserted through the opening in the skin in the puncture site prior to or simultaneously with compression member insertion. See figure 3G.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers, as applied to claim 1 above.

Myers does not specifically disclose deploying the expansible member within a blood vessel having a diameter in a range from about 0.05 inch to about 0.5 inch.

However, doing so would be obvious to one having ordinary skill in the art at the time of the invention because of the varying sizes of patient's blood vessels.

Further, Myers does not specifically disclose imaging the expansible element during positioning. However, doing so would be obvious to one having ordinary skill in the art at the time of the invention because it would allow the physician to perform the hemostasis more easily. Also, see col. 4, lines 65-67 where Myers discloses the use of ultrasound imaging to determine the thickness of the patient's blood vessel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barak, U.S. 5,728,134, disclosing a method and apparatus for hemostasis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

January 29, 2007

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER